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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,689	03/26/2002	Carla Bevilacqua	0471-0268P	8180

2292 7590 07/24/2003

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EXAMINER
COOK, REBECCA

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 07/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N . 10/009,689	Applicant(s) BEVILACQUA ET AL.	
	Examiner Rebecca Cook	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with th c rresp ndenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/13/03* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 7 and13 are objected to because of the following informalities: the word chloricromene is misspelled. Appropriate correction is required.

Claims 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The intent of the method of claim 7 is confusing. Amending it to recite "A method of treating hypercholesterolaemia in a patient in need thereof comprising administering..." will overcome this rejection.

The use of the plural "patients with cholesterol levels" in claim 10 is confusing as to who the intended subject is, since claim 7 recites "patient" in the singular. Amending claim 10 to recite "a patient with a cholesterol level" will overcome this rejection.

In claim 11 it is not clear of more than one form of capsule, tablet, etc is required. Amending each form to recite singular will overcome this rejection. Also, it is not clear how the controlled release systems distinguish over transdermal systems, capsules, tablets and injectable solutions, since controlled release systems include transdermal systems, capsules, tablets and injectable solutions. Amending the claim to delete "controlled release systems" will overcome this rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by 4,349,566 or 4,362,741.

'566 and '741 each disclose (column 1, column 4 lines 8-12) a pharmaceutical composition comprising cloicromene. The instant claim appears to differ over the references in reciting an intended use and dose. However, the instant dosage is within the disclosed dosage range and intended use does not impart patentability to a composition claim.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoult. Hoult (entire abstract, page 715, left-hand column through page 717, left-hand column) discloses that coumarins are known to reduce cholesterol. Hoult additionally discloses that chloricromene possesses antithrombotic antiplatelet actions. Instant dependent claims differ over Hoult in reciting patient cholesterol levels, the form of the composition and a chloricromene salt. However, once a method of using a compound is known it is within the skill of the artisan to determine the form of the pharmaceutical composition and salt of the active compound and the instant claims do not recite a composition or salt that has unique properties that would be unobvious to one of ordinary skill in the art. Furthermore, from the data presented on page 716, one of

ordinary skill in the art would expect that the composition would be active in a patient with cholesterol plasma levels over 190 mg/dl.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

REBECCA COOK
PRIMARY EXAMINER
GROUP 1200 / 6 / 4

July 18, 2003